Remarks/Arguments:

This is a reply to the office action of July 24. The claims then presented were rejected over four references (U.S. Patent No. 5856174 to Lipschutz et al., WO 99/33559 A1 Pourahmadi et al., WO 01/92569 Oultram et al. and the Gribanov et al. article) which are discussed below.

The claims have been amended above to comply with formal requirements, and claim 37 has been substantially amended to overcome the prior art rejections.

The abstract has been revised to comply with the rules.

The present invention provides a cartridge which is constructed in a very simple manner, much simpler than the prior art devices. The sample simply rises through the cartridge in a vertical direction; there are no horizontal passages such as e.g. in Lipshutz's device.

A lyophilizate (i.e. a freeze-dried composition) is provided within the vertical flow at one membrane, so that when the sample flows through the cartridge in a vertical direction, the lyophilizate is taken up by the sample.

Turning now to the claim amendments, we have cancelled all claims which were withdrawn from consideration due to the restriction requirement. Thus, the only independent claim presented is claim 37. We have included into claim 37 the composition according to original claim 1, in order to address the objection of the examiner that claim 37 was dependent from a claim which is no longer under consideration.

Claim 37 is a now combination of previous claims 37, 38, 40 and 41. Thus, claim 37 states that the unit is a cartridge. It also recites that the composition is in the form of a lyophilizate, and that it is bound to a membrane. Moreover, the cartridge is constructed in a way that allows the sample to flow through in the vertical direction. Support for this limitation can be found in the specification on page 5 at lines 9 to 11.

In the devices of the prior art, the sample flows through the respective devices in a very complicated manner involving horizontal segments. It is clear that in the devices of the prior art the sample has to be forced to flow through the device. This is not necessary with the device of the present invention, which results in easier and cheaper manufacture.

Moreover, claim 37 now requires that the sample be mixed with the composition (lyophilizate) when passing through the membrane in order to provide the reaction mixture. Support for this can be found in the paragraph bridging pages 4 and 5.

Claims 38, 40, 41 and 52 have been canceled.

Claims 39, 42 to 51 were amended so as to refer to a cartridge instead of a unit.

Claim 53 to 56 were also amended by replacing the term “unit” with “cartridge”.

The same applies to claims 66 to 72. Please also note that we have replaced the phrase “where appropriate” by “optionally" as suggested by the examiner.

Turning to the issue of novelty, we do not agree that Lipschutz discloses a cartridge in accordance with amended claim 37. First of all, as already explained above, the cartridge of the present invention allows a sample to flow directly through the cartridge. This is not possible in Lipschutz, as can be easily seen from, for example, Figure 3 of

Lipschutz. There is at least one passage in the flow of the sample through the device of Lipschutz where a horizontal flow is required. In this respect, the sample has to be forced to flow through the device of Lipschutz, which is not necessary with the device of the present invention.

Secondly, Lipschutz does not provide a clear and unambiguous disclosure that a lyophilizate is bound to at least one membrane so that the sample is mixed with said lyophilizate when passing through the membrane in order to provide the reaction mixture. From a careful reading of the passage at column 8, lines 23 to 32 of Lipschutz, we conclude that a differentiation is made: while the preceding section (column 8, lines 18 to 19) states that the reagents may be in lyophilized form, there is no disclosure that an entire composition comprising all reagents necessary e.g. for performing a PCR reaction may be bound to a membrane. The paragraph beginning at line 23 describes that the enzyme may be coupled to a suitable solid support. However, in that section only the enzyme is discussed, not an entire composition comprising other reagents as well. Moreover, in the section discussing the binding to a solid support of the enzyme there is no mention whatsoever of lyophilization. Quite to the contrary, column 8, lines 31 to 32 even states that it would not be necessary to lyophilize the enzyme. Thus, Lipschutz not only does not provide a clear and unambiguous disclosure of binding an entire composition comprising all reagents necessary for performing a PCR reaction in form of a lyophilizate to a membrane, he actually teaches away from it by saying it would not be necessary to carry out such a lyophilization.

In applicant's opinion, Lipschutz not only does not anticipate the present claims, but also is incapable of rendering the subject matter of those claims obvious. Lipschutz clearly did not recognize the benefits of providing the entire composition comprising all reagents necessary for carrying out a PCR reaction in form of a lyophilizate bound to a membrane. The advantages of that step are a very simple, easy to perform and

cheap method of providing a reaction mixture for e.g. a PCR reaction. Lipschutz's device is more complicated than the device of the present application.

In summary, applicant believes that the present claims are patentable over Lipschutz.

As far as the second reference (Pourahmadi) is concerned, basically the same arguments apply. It has to be noted that Pourahmadi's device is even more complicated and complex, requiring electronic circuits for controlling the flow of the sample through said device. This is by no means the same as the very simple cartridge of the present invention. Also in Pourahmadi's device, the sample has to be forced to flow through the device, since there are several passages where flow in a horizontal direction is required.

Secondly, Pourahmadi fails to disclose the important feature of the present invention that a composition comprising all reagents necessary for carrying out a PCR reaction is bound in lyophilized form to a membrane. From the passage at page 23, line 4, to page 25 line 10, applicant cannot find a disclosure of that feature. The passage identified mentions that reagents may be exogenously introduced into the cartridge before use, but there is no disclosure of using a lyophilizate, let alone to bind such a lyophilizate to a membrane. It is correct that on page 24, lines 26 to 29, it is suggested to use common techniques such as lyophilization to stabilize reagents containing compounds that are thermally unstable. However, even here there is no disclosure whatsoever that such reagents may be bound to a membrane. It is also not disclosed that an entire composition comprising all reagents necessary for performing a PCR reaction should be provided together in form of a lyophilizate and bound to said membrane.

Applicant is of the firm opinion that Pourahmadi does for the above reasons not anticipate or render obvious the subject matter of the claims on file.

Oultram (WO 01/92569) is not capable of rendering obvious the subject matter of the present claims on its own. Oultram is related to a lyophilizate in general. However, Oultram does not suggest binding such a lyophilizate to a membrane in order to prepare a reaction mixture – e.g., a PCR reaction – in a simple manner. Oultram does not suggest or disclose a cartridge as defined in the present claims. Oultram does not overcome the deficiencies of Pourahmadi, since it does not render obvious the essential feature that is also lacking from Pourahmadi. Thus, even a combination of Oultram and Pourahmadi would not render obvious the subject matter of the instant claims.

The Gribanov reference is not addressed in view of the cancellation of claim 52, against which Gribanov was applied.

In summary, applicant believes that the amended claims now presented are patentable over the prior art cited by the examiner. It is therefore kindly requested that a notice of allowance be issued.

Respectfully,

/Charles Fallow/

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